IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

LIFEWAY FOODS, INC., an Illinois corporation, JULIE SMOLYANSKY, and EDWARD SMOLYANSKY, individuals,

Defendants.

Case No. _____

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, by its attorney, Patrick J. Fitzgerald, United States Attorney for the Northern District of Illinois, complains as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought on behalf of the United States Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 332(a), and the Court's inherent equitable power, to enjoin and restrain Lifeway Foods, Inc. ("Lifeway"), a corporation, and Julie Smolyansky and Edward Smolyansky, individuals, (hereinafter, collectively, "Defendants") from violating:

A. 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of food, specifically cream cheese, cream cheese spreads, and seafood products, that are adulterated within the meaning of 21 U.S.C. § 342(a)(4), and/or

misbranded within the meaning of 21 U.S.C. §§ 343(q)(2)(A), 343(w)(1), 343(i)(2), and 343(a)(1); and

B. 21 U.S.C. § 331(k) by causing those articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), and/or causing those articles of food to become misbranded within the meaning of 21 U.S.C. §§ 343(q)(2)(A), 343(w)(1), 343(i)(2), and 343(a)(1), while such articles are held for sale after shipment in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a), and personal jurisdiction over all parties.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

THE DEFENDANTS

4. Defendant Lifeway, is a publicly owned corporation, incorporated under the laws of the State of Illinois, with its corporate headquarters and principal place of business located at 6431 W. Oakton Street, Morton Grove, Illinois ("Morton Grove facility"), within the jurisdiction of this Court.

5. Defendant Lifeway also owns and operates manufacturing and storage facilities at 5201 Harbison Avenue, Philadelphia, Pennsylvania ("Philadelphia facility"), and 7625 N. Austin Avenue, Skokie, Illinois ("Skokie facility").

6. Defendant Julie Smolyansky, an individual, is the President and Chief Executive Officer of Lifeway. Julie Smolyansky is responsible for all aspects of the firm's operations, including label design and content, seafood Hazard Analysis and Critical Control Point ("HACCP") plan implementation, and employee training. She has personally responded to FDA

correspondence regarding corrective actions to be taken at both the Philadelphia and Skokie facilities. Ms. Smolyansky primarily performs her duties at Lifeway's Morton Grove facility.

7. Defendant Edward Smolyansky, Ms. Smolyansky's brother, is the Chief Financial Officer of Lifeway. Edward Smolyansky evaluates budgets, provides approval to make equipment purchases, and is involved in new product development. The plant managers for Lifeway's Philadelphia, Skokie, and Morton Grove facilities report directly to Mr. Smolyansky, as do Lifeway's accounting, production, and maintenance groups. Mr. Smolyansky performs his duties primarily from Lifeway's Morton Grove facility.

8. Lifeway's principal business activity involves the processing and distribution of dairy and non-dairy food products, including kefir (a dairy beverage similar to yogurt), soy-based kefir, farmer cheeses, spreadable cheese products, and various products labeled as cream cheeses or cream cheese spreads (hereinafter collectively referred to as "cream cheese products").

9. Defendants have been, and are now, engaged in processing, packing, holding, labeling, and distributing in interstate commerce over 30 varieties of plain, "lite," flavored, and seafood-containing cream cheese products, and various articles of ready-to-eat seafood products, including Acme Whitefish Salad and ground nova salmon (hereinafter collectively, with the seafood-containing cream cheese products, referred to as "seafood products"). These items constitute food within the meaning of 21 U.S.C. § 321(f). Lifeway's seafood products are also fishery products within the meaning of 21 C.F.R. § 123.3(e).

10. Defendants distribute their cream cheese products and seafood products to customers in New Jersey and Pennsylvania. Further, Defendants receive ingredients for use in

their cream cheese products and seafood products from outside of Illinois and Pennsylvania, including salmon from New York, cream cheese from Vermont, and sour cream from Minnesota.

DEFENDANTS' VIOLATIONS

11. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce adulterated and misbranded food.

12. Defendants also violate 21 U.S.C. § 331(k) by causing food held for sale after shipment in interstate commerce to become adulterated and misbranded.

Adulteration

13. To ensure the safety of food containing fish, FDA promulgated the seafood HACCP regulation in 1995. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65,096 (Dec. 18, 1995) (codified at 21 C.F.R. Pt. 123 as amended).

14. Every processor of fish and fishery products ("fish processor") must follow the requirements set forth in the seafood HACCP regulation, 21 C.F.R. Pt. 123. Failure to adhere to these requirements renders the products adulterated under 21 U.S.C. § 342(a)(4). 21 C.F.R. § 123.6(g).

15. The seafood HACCP regulation requires that every fish processor conduct, or have conducted for it, a hazard analysis to determine whether there are any food safety hazards that are reasonably likely to occur during the processing of each kind of fish and fishery product that it produces. 21 C.F.R. § 123.6(a). Whenever a hazard analysis identifies one or more food safety hazards that are reasonably likely to occur, the fish processor must have and implement an adequate HACCP plan to identify and control such food safety hazards. 21 C.F.R. § 123.6(b).

Among other requirements, the HACCP plan must identify critical control points to prevent, eliminate, or reduce identified food safety hazards to acceptable levels. 21 C.F.R. § 123.6(c).

16. Defendants have failed to conduct a hazard analysis, and have not developed and implemented an adequate HACCP plan for each seafood product that they process, pack, hold, label or distribute at the Philadelphia and Skokie facilities.

17. Every fish processor must also monitor the sanitation conditions and practices during processing with sufficient frequency to ensure conformance with Current Good Manufacturing Practice ("CGMP") as set forth at 21 C.F.R. Pt. 110, and must maintain records that document such sanitation monitoring. 21 C.F.R. § 123.11(b) and 123.11(c).

18. Defendants have failed to document the required monitoring of sanitation conditions and practices with sufficient frequency to ensure conformance with CGMP, including cleanliness of food contact surfaces, prevention of cross-contamination from insanitary objects, and maintenance of hand washing, hand sanitizing, and toilet facilities.

19. Therefore, Defendants' seafood products are adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

Misbranding

(a) Failure to label* trans *fat content

20. To assist consumers in maintaining healthy dietary practices, FDA issued a final rule on July 11, 2003, requiring nutrition labels to declare *trans* fat amounts on a separate line, immediately under saturated fats. Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41,434 (July 11, 2003) (codified at 21

C.F.R. § 101.9(c)). To minimize the need for multiple labeling changes and to provide small businesses ample time to use current label inventories and phase in label changes, FDA set the effective date for the new requirements as January 1, 2006, nearly two and a half years later. *Id.* at 41,466 (preamble). Failure to adhere to this requirement renders the food "misbranded" within the meaning of 21 U.S.C. § 343(q)(2)(A).

21. Many of Defendants' cream cheese products are misbranded within the meaning of 21 U.S.C. § 343(q)(2)(A), in that their Nutrition Facts panels fail to declare *trans* fat. The cream cheese products that do not have Nutrition Facts panels that declare *trans* fat include the following: strawberry; scallions; chives; vegetable; jalapeno; plain whipped; sun dried tomatoes; apricot; apples, raisins and cinnamon; garlic and herbs; roasted red pepper; honey mustard; cheddar cheese with horseradish; plain lite; chives lite; apples, raisin and cinnamon lite; garlic and herbs lite; vegetable lite; lox; lox and onion; and lox lite.

(b) Failure to declare major food allergen

22. In 2004, Congress enacted the Food Allergen Labeling and Consumer Protection Act of 2004 ("FALCPA"), Pub. L. No. 108-282, Tit. II, 118 Stat. 891, 905 (codified in pertinent part at 21 U.S.C. §§ 321(qq) and 343(w)). In this statute, Congress found that approximately two percent of adults and five percent of infants and young children in the United States suffer from food allergies; that food allergies are incurable; that approximately 30,000 individuals require hospitalization per year; and that 150 people die from allergic reactions to food annually. *Id.* § 202, 118 Stat. at 906. In enacting FALCPA's requirement for producers to list food allergens on labels, Congress stated that "consumers need to be empowered to know whether or not food allergens are present in the food they consume." H.R. Rep. No. 108-608, at 3 (2004).

FALCPA's food allergen labeling requirements were signed into law August 2, 2004, and took effect on January 1, 2006. FALCPA § 203(d), 118 Stat. at 908.

23. Failure to list a major food allergen on a product label renders the food misbranded. 21 U.S.C. § 343(w)(1). The Act defines "major food allergen" to include "fish" 21 U.S.C. § 321(qq)(1).

24. Defendants' lox lite cream cheese is misbranded within the meaning of 21 U.S.C. § 343(w)(1) in that its label fails to declare the major food allergen salmon.

(c) Failure to list each ingredient, including all sub-ingredients

25. Under 21 C.F.R. § 101.4(b)(2), a product label for food must list the common or usual name of each ingredient contained in the product, including sub-ingredients (ingredients of an ingredient in the finished product) when the product is fabricated from two or more ingredients. Failure to adhere to this requirement renders a product misbranded under 21 U.S.C. § 343(i)(2).

26. Defendants' cream cheese products are processed with two types of cream cheese plus sour cream. Many of Defendants' product labels fail to declare sub-ingredients of the sour cream and cream cheese, including but not limited to, milk proteins and cultured pasteurized Grade A skim milk. Therefore, these cream cheese products are misbranded within the meaning of 21 U.S.C. § 343(i)(2). The cream cheese products with labels that do not declare their sub-ingredients include the following: sun dried tomatoes; apricot; apples, raisins, and cinnamon; garlic and herbs; roasted red pepper; honey mustard; cheddar cheese with horseradish; plain lite; chives lite; apples, raisin and cinnamon lite; garlic and herbs lite; vegetable lite; and lox lite.

(d) False and misleading protein amounts declared

27. Defendants' plain whipped cream cheese spread is misbranded within the meaning of 21 U.S.C. § 343(a)(1), in that its product label is false or misleading. Defendants' label for this food product declares that it contains 2 grams of protein per serving. However, FDA analyses of samples taken from the Philadelphia facility in July 2006 and March 2007 found, on both occasions, only 1.3 grams of protein per serving – approximately 65% of the protein value declared on the product label.

MOST RECENT FDA INSPECTIONS

28. Defendants have an extensive history of failing to have or implement a HACCP plan for their seafood-containing cream cheese products and other seafood products, as well as a history of repeated violations in the product labeling for their cream cheese products. Multiple FDA inspections, conducted since December 2004, document a consistent pattern of violative conduct. While Defendants have repeatedly promised to correct these violations, FDA's inspections show that these promises have not been kept, as evidenced by recent FDA inspections at Defendants' facilities.

Philadelphia Facility Inspections in March and August 2007

29. FDA inspected the Philadelphia facility in March 2007 and August 2007. The inspections found that Defendants failed to comply with HACCP regulations, by failing to conduct a hazard analysis, and failing to have and implement a HACCP plan for each type of seafood product that Defendants processed, packed, held, labeled, and/or distributed at the facility. The August 2007 inspection of the Philadelphia facility also found that Defendants failed to document the required monitoring of sanitation conditions and practices with sufficient

frequency to ensure conformance with CGMP, including cleanliness of food contact surfaces, prevention of cross-contamination from insanitary objects, and maintenance of hand washing, hand sanitizing, and toilet facilities.

30. The March 2007 and August 2007 Philadelphia inspections also found labeling violations for many plain, lite, flavored, and seafood-containing cream cheese products. Specifically, these inspections found that these products failed to list *trans* fat content in their Nutrition Facts panels, failed to list the major food allergen salmon, and failed to list the common or usual name of each sub-ingredient when the product was fabricated from two or more ingredients.

31. In addition, FDA collected samples of Defendants' plain whipped cream cheese spread during the March 2007 inspection of the Philadelphia facility. FDA analyses of these samples indicated an actual protein value of 1.3 grams, approximately 65% of the declared protein value of 2 grams on the Nutrition Facts label for Defendants' plain whipped cream cheese spread.

Skokie Facility Inspections in March/May and August 2007

32. FDA conducted an inspection of the Skokie facility in March and May 2007. That inspection found HACCP violations including the failure to have and implement a HACCP plan for each type of seafood product that Defendants processed, packed, held, labeled, and/or distributed at the Skokie facility. Moreover, the inspection found that Defendants failed to document the required monitoring of sanitation conditions and practices for their seafood products with sufficient frequency to ensure conformance with CGMP, including cleanliness of

food contact surfaces, prevention of cross-contamination from insanitary objects, and maintenance of hand washing, hand sanitizing, and toilet facilities.

33. FDA investigators conducted another inspection of the Skokie facility in August 2007. At that time, Edward Smolyansky explained that the Skokie facility had ceased the production of cream cheese products in July 2007.

34. During the March/May 2007 inspection, Mr. Smolyansky had admitted that Lifeway's Skokie facility did not have a seafood HACCP plan for cream cheese with lox, yet, as of the August 2007 inspections FDA investigators confirmed that Defendants still did not have a seafood HACCP plan for the Philadelphia facility and had not implemented a HACCP plan for the Skokie facility while producing seafood-containing cream cheese products through July 2007.

PREVIOUS FDA INSPECTIONS

35. Defendants' HACCP and labeling violations were well documented on multiple prior inspections of the Philadelphia facility in December 2004, April 2005, July 2006, and August 2006; and at the Skokie facility in August/September 2006.

36. FDA's inspections at the Philadelphia facility in December 2004 and again in April 2005 documented HACCP violations including Defendants' failure to have and implement a HACCP plan, and failure to monitor and/or document the required monitoring of the sanitation conditions and practices.

37. At the close of the December 2004 Philadelphia inspection, on December 10, 2004, the FDA investigator held a conference call with Defendants Julie and Edward Smolyansky. Among other violations, the FDA investigator discussed with them Defendants'

failure to have HACCP plans as required. Defendant Julie Smolyansky stated that Lifeway would implement a seafood HACCP plan the following week.

38. FDA's next two inspections at the Philadelphia facility were in July and August 2006. These were the first inspections following the effective date of the *trans* fat and major food allergen labeling requirements. These inspections again documented HACCP violations, including a failure to conduct a hazard analysis and failure to develop and implement a HACCP plan. Further, FDA investigators documented during both the July and August 2006 inspections of the Philadelphia facility that Defendants were using violative labels for many of their cream cheese products, in that the labels failed to list the major food allergen salmon and/or failed to list all sub-ingredients by common or usual name. During the inspection, an FDA investigator discussed the allergen and *trans* fat labeling requirements with the plant manager of the Philadelphia facility, and provided FDA's website guidance for industry.

39. In addition, FDA analysis of Defendants' plain whipped cream cheese spread obtained during the July 2006 inspection indicated an actual protein value of 1.3 grams per serving, approximately 65 percent of the declared 2 grams of protein listed on the product label.

40. FDA inspected the Skokie facility in August/September 2006. This inspection found a failure to have and implement a HACCP plan and failure to document the required monitoring of the sanitation conditions and practices. At the close of this inspection, on September 7, 2006, the FDA investigator advised Defendant Julie Smolyansky that the firm needed to prepare a seafood HACCP plan as soon as possible. On the same day, Defendant Edward Smolyansky advised the FDA inspector that Lifeway would prepare a seafood HACCP plan.

FDA WARNINGS TO DEFENDANTS

41. At the conclusion of each inspection at the Philadelphia facility in December 2004, April 2005, July 2006, March 2007, and August 2007, and at the Skokie facility in August 2006 and March/May 2007, the FDA investigator issued a Form FDA 483 ("Form 483") List of Inspectional Observations to the plant manager documenting violations seen during the inspection. In addition, an FDA investigator issued a Form 483 to Ms. Smolyansky after the August 2006 inspection of the Skokie facility, and another to Mr. Smolyansky after the March/May 2007 inspection of the Skokie facility.

42. FDA also issued Defendants a Warning Letter dated August 9, 2005, outlining the HACCP violations, including a failure to conduct a hazard analysis, failure to develop and implement a HACCP plan, and failure to document the required monitoring of sanitation conditions and practices. FDA's Warning Letter also outlined various labeling violations, including failure to list the major food allergen salmon and failure to list sub-ingredients by their common or usual name. In the Warning Letter, FDA warned that it could initiate enforcement action, including seizure or injunction, without further notice.

43. In a written response dated September 1, 2005, Defendant Julie Smolyansky provided FDA with a copy of Lifeway's proposed HACCP plan, and she promised that by November 1, 2005, all labels "will bear a complete list of all ingredients by common name," and all labels that "require allergen statements will be changed." In a written reply on October 3, 2005, FDA informed Defendants that the HACCP plan was inadequate.

44. Seven months later, in a letter dated May 3, 2006, Defendant Julie Smolyansky again notified FDA that Lifeway would cease using old (violative) labels by May 22, 2006.

45. Defendants failed to take corrective action as evidenced by the continuing HACCP and labeling violations observed by the FDA investigators during the inspections at the Philadelphia facility in July and August 2006 and the Skokie facility in August 2006.

46. FDA sent another letter, dated October 20, 2006, to Defendants Julie Smolyansky and Lifeway, setting out many of Defendants' labeling violations, including failure to list the major food allergen salmon and failure to list sub-ingredients by their common or usual name. In the letter, FDA further informed Defendants Julie Smolyansky and Lifeway that, under 21 C.F.R. § 101.9(c)(2)(ii), Defendants were required to list the *trans* fat content in the Nutrition Facts panel on product labels.

47. On November 15, 2006, representatives from FDA had a conference call with Defendant Julie Smolyansky to discuss Defendants' continuing HACCP and labeling violations. At the conclusion of the call, Ms. Smolyansky promised that by the end of January 2007, Defendants would implement a HACCP plan at the Philadelphia facility and correct all labeling problems.

48. Defendants' promises to take corrective action were not kept. As set forth above, FDA inspections at the Philadelphia facility in March 2007 and August 2007, and at the Skokie facility in March/May 2007 documented continuing HACCP and labeling violations.

REQUEST FOR RELIEF

49. Despite numerous warnings from FDA and repeated promises to bring their actions into conformity with the law, Defendants continue to violate the Act.

50. Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and 331(k) in the manner set forth above.

WHEREFORE, THE PLAINTIFF PRAYS:

I. That Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of the Court's Order, be permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly violating:

A. 21 U.S.C. § 331(a), by introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, any article of food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4), and/or misbranded within the meaning of 21 U.S.C. § 343; and

B. 21 U.S.C. § 331(k), by causing food held for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), and/or misbranded within the meaning of 21 U.S.C. § 343.

II. That the Court order Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of the Court's Order, to cease processing, packing, holding, labeling, and/or distributing any food at the Philadelphia and Skokie facilities, and any location from which Defendants process, pack, hold, label, and/or distribute any food, unless and until Defendants bring their operations and facilities into compliance with the Act and applicable regulations to FDA's satisfaction.

III. That the Court award Plaintiff its costs incurred in pursuing this action and such other relief as the Court may deem just and proper.

Respectfully submitted,

Dated: April 30, 2008
Washington, DC

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